



Dkt. 7156/52427-AB/JPW/GJG/BJA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Don Fishbein
Serial No. : 10/799,197 Examiner: Alicia R. Hughes
Filed : March 12, 2004 Group Art Unit:1614
For : USE OF OXANDROLONE IN THE TREATMENT OF BURNS AND
OTHER WOUNDS

30 Rockefeller Plaza, 20th Fl.
New York, New York 10112
March 13, 2009

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION IN RESPONSE TO FEBRUARY 23, 2009 ADVISORY ACTION
AND PETITION FOR TWO-MONTH EXTENSION OF TIME

This Communication is submitted in connection with the above-identified application and further to the Notice of Appeal filed on November 10, 2008 with the U.S. Patent and Trademark Office in connection with the above-identified application. In addition, this Communication addresses comments made by the Examiner in the February 23, 2009 Advisory Action issued in connection with the above-identified application. The November 10, 2009 Notice of Appeal was received on November 13, 2008 by the U.S. Patent and Trademark Office. A copy of the stamped returned postcard is attached hereto as **Exhibit A**. Accordingly, a response was due January 13, 2009. Applicant hereby petitions for a two-month extension of time to respond. The fee for a two-month extension of time is FOUR HUNDRED AND NINETY DOLLARS (\$490.00), and a check including this amount is enclosed. With a two-month extension of time, a response is now due March 13, 2009. Accordingly, this Communication and accompanying Request for Continued Examination are being timely filed.

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Applicant : Don Fishbein
Serial No. : 10/799,197
Filed : March 12, 2004
Page 2 of 3

Applicant notes that in the February 23, 2009 Advisory Action the Examiner indicated that the November 10, 2008 Response raises issues requiring further consideration and/or search, and that "evidentiary materials" in their November 10, 2008 Response required close examination by the Examiner. As a result, the Examiner maintained the obviousness rejections of claims 30-40 and 41-45 based on the Examiner's previous "reasons made previously of record". However, these reasons do not take into consideration the unpredictability issue as pointed out on pages 2 to 5 of applicant's November 10, 2008 Response and the fact that, even if one accepts the argument that oxandrolone increases appetite, this does not predictably lead to weight gain in burn victims because of the issues described in the November 10, 2008 Response and evidenced by the Sheffield-Moore et al. paper submitted with the Response (the "evidentiary materials" referred to by the Examiner and not yet considered).

Applicant further notes, with regard to the specific obviousness rejection of claims 30 and 41 over Berger in view of Schaffer and Labrie et al., that applicant asserted in their November 10, 2008 Response that Berger in view of Schaffer do not teach the claimed method and that Labrie et al. do not cure the deficiency. The Examiner stated in the February 23, 2009 Advisory Action that "No reason is given for this assertion". To clarify, applicant notes that the invention claimed in claims 30 and 41 is not obvious over Berger in view of Schaffer for the same reasons as articulated on pages 2-5 of their November 10, 2008 Response. When Labrie et al. is viewed in combination with Berger in view of Schaffer, the combination still does not render the claimed invention obvious because Labrie et al., disclosing sustained release compositions, does not address and does nothing to cure the predictability issues based on etiology of weight loss and the unpredictability of any weight gain in burn victims due to issues described the November 10, 2008 Response and evidenced by the Sheffield-Moore et al. paper.

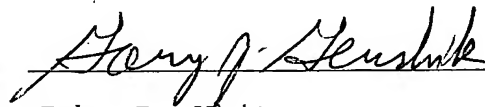
Applicant : Don Fishbein
Serial No. : 10/799,197
Filed : March 12, 2004
Page 3 of 3

Accordingly, applicant maintains that the currently claimed invention is non-obvious over the combinations of art cited by the Examiner for the reasons as presented in their November 10, 2008 Response and clarified herein.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invites the Examiner to telephone him at the number provided below.

No fee, other than the enclosed fee of \$1,300.00 fee, including a Request for Continued Examination fee of \$810.00 and a two-month extension of time fee of \$490.00, is deemed necessary in connection with the filing of this Communication. However, if an additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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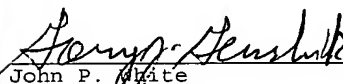
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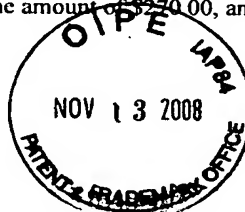
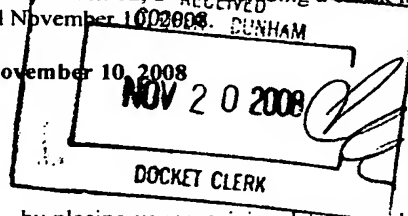
EXHIBIT A

Applicant Don Fishbein
Client SAVIENT(7156) File No. 52427-AB Atty. JPW/GJG/JDF
Date November 10, 2008

Kindly acknowledge receipt of the accompanying

**NOTICE OF APPEAL FROM THE EXAMINER'S DECISION TO THE BOARD OF
PATENT APPEALS AND INTERFERENCES** in connection with Don Fishbein., USE OF
OXANDROLONE IN THE TREATMENT OF BURNS AND OTHER WOUNDS, U.S. Serial No.
10/799,197, filed March 12, 2004, including a check in the amount of \$270.00, and Certificate of
Mailing dated November 10, 2008.

Due Date: November 10, 2008



by placing your receiving date stamp hereon and returning to us.